

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

----- x

NISKAYUNA OPERATING CO., LLC, :

Plaintiff, :

1:10 Civ. 1265
(GLS/DRH)

-against- :

KATHLEEN SEBELIUS, as Secretary of the United States :
Department of Health and Human Services, DONALD
BERWICK, as Administrator of the Centers for Medicare :
& Medicaid Services, and RICHARD F. DAINES, M.D.,
as Commissioner of Health of the State of New York, :

AFFIDAVIT

Defendants. :

----- x

STATE OF NEW YORK)

) ss:

COUNTY OF NASSAU)

BETSY MALIK, affirms under the penalties of perjury:

1. I am a healthcare regulatory attorney and have been practicing in that capacity since 2002, at the law firm of Abrams, Fensterman, Fensterman, Eisman, Greenberg, Formato & Einiger, LLP, attorneys for the plaintiff Niskayuna Operating Co., LLC. My area of practice consists of counseling nursing facilities in New York on regulatory and compliance issues, so I am familiar with the federal and state survey and certification process. The purpose of this affidavit is to provide some relevant background information on the state and federal survey and certification process.

2. Skilled nursing facilities (familiarily referred to as nursing homes) electing to provide services to Medicare and Medicaid beneficiaries must enter into a provider agreement with the United States Department of Health and Human Services ("HHS") whereby they agree to comply

Abrams, Fensterman, Fensterman, Eisman, Greenberg, Formato & Einiger, LLP
1111 Marcus Avenue, Suite 107
Lake Success, NY 11042

with the terms and conditions of participation. The Center for Medicare and Medicaid Services (“CMS”), a federal agency, has been appointed by HHS to administer the program requirements. As a condition of participation in the Medicare and Medicaid programs, nursing homes must comply with federal and state law that governs every aspect of nursing home care and operations. See 42 U.S.C. §§1396r, 1395i-3; 42 C.F.R §483; NY Public Health Law §2803 and 10 N.Y.C.R.R. Part 415. Regulations have also been adopted which set forth the requirements that nursing facilities must follow.

3. Medicare has contracted with state agencies to evaluate nursing facilities’ compliance with the regulatory requirements. 42 U.S.C. §1395i-3; 42 C.F.R §488.330(a)(1)(I); 42 C.F.R §488.10. The New York State Department of Health (“DOH”) is designated the state survey agency to verify and validate compliance with the federal and state regulatory requirements. A standardized survey protocol with the extensive procedures to follow during the survey is embodied in the State Operations Manual (“SOM”).

4. The SOM provides in Appendix PP extensive interpretive guidelines for each regulation set forth at 42 C.F.R. Part 483. Each regulation is assigned an F-tag.

5. While there are various types of surveys, of relevance to this action is the standard survey that must be conducted unannounced within twelve months of the previous standard survey but no later than fifteen months. Facilities that have a poor performance record are considered special focus facilities. DOH conducts two certification surveys per year of facilities under this designation. A facility must show significant improvements while under this designation in order to be removed from this category. Significant improvement means no harm has occurred to residents according to the survey history during this time frame. CMS can elect to terminate the special focus

facility's participation in the Medicare program at any time if deficiencies are not corrected.

6. If a facility is found non compliant with a participation requirement, it is cited a deficiency or a F-tag and the corresponding regulation that is violated. The scope (number of individuals affected by the violation) and severity (level of harm to the resident, if any) of each deficiency is also indicated by the assignment of a letter from A-L.

7. Scope can be any one of three levels. "Isolated" means one or a very limited number of residents are affected. "Pattern" means the effect of the deficient practice is to a subset of the resident population but it is not pervasive. "Widespread" means the problems causing the deficiencies are pervasive.

8. Severity is divided into four levels. Level 1 is a deficiency that has no actual harm with the potential for minimal harm. Level 2 is a deficiency, again, with no actual harm but with the potential for more than minimal harm. Level 3 is a deficient practice that caused or resulted in actual harm but that is not immediate jeopardy. Level 4 immediate jeopardy means a provider's non-compliance has caused or, is likely to cause immediate or imminent serious harm to resident health or safety.

9. DOH and CMS take the scope and severity of the deficiency into consideration in recommending and determining the remedies to be imposed against the facility. The following chart from the State Operations Manual, Chapter 7, §7400.5 best illustrates the factors used to determine the seriousness of the deficiencies:

Immediate jeopardy to resident health or safety	J PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	K PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	L PoC Required: Cat. 3 Optional: Cat. 2 Optional: Cat. 1
---	--	--	--

Actual harm that is not immediate jeopardy	G PoC Required*: Cat. 2 Optional: Cat. 1	H PoC Required*: Cat. 2 Optional: Cat. 1	I PoC Required*: Cat. 2 Optional: Cat. 1 Optional: Temporary Mgmt.
No actual harm with potential for more than minimal harm that is not immediate jeopardy	D PoC Required*: Cat. 1 Optional: Cat. 2	E PoC Required*: Cat. 1 Optional: Cat. 2	F PoC Required*: Cat. 2 Optional: 000000000000 000000000000000000 Optional: Cat. 1
No actual harm with potential for minimal harm	A No PoC No Remedies Commitment to Correct Not on HCFA-2567	B PoC	C PoC
	Isolated	Pattern	Widespread

10. Deficiencies are documented in a form report (CMS 2567L) known as the Statement of Deficiencies (“SOD”). The SOD is intended to be a stand alone document that lays out the state agency’s case.

11. Each facility that has been cited deficiencies must submit a plan of correction (“POC”) within 10 calendar days from the date of the SOD. The POC is the facility’s credible allegation of compliance. Its objective is to explain how it will correct and implement the corrective measures it has adopted.

Administrative Appeal/Hearing

12. Facilities seeking to challenge the survey findings can submit a request for informal dispute resolution ("IDR") within 10 days of the date of the SOD. 42 C.F.R. §488.331. The IDR is an administrative process within the DOH to dispute the cited deficiencies. In an IDR, the facility cannot challenge the scope or severity level unless immediate jeopardy or substandard quality of care is found nor can it challenge the remedy imposed, the propriety of the survey process or the surveyor's actions.

13. Facilities may also pursue a federal administrative appeal procedure to challenge the survey findings and conclusions of non compliance before the federal Departmental Appeals Board ("DAB"). 42 U.S.C. §1320a-7(f)(2); 42 C.F.R. §488.408(g). The federal appeal process can only be invoked if the facility is issued a remedy as specified in 42 C.F.R. §488.406. In other words, unless an appealable remedy is imposed, the facility does not have an automatic right to a hearing before the DAB. Facilities seeking to appeal must file a written request for a hearing before the DAB within 60 days of notice of the initial determination from the CMS.


BETSY MALIK

Sworn to before me on
October 24, 2010


Notary Public

SARAH C. LICHTENSTEIN
Notary Public, State of New York
No. 02LI4709172
Qualified in Suffolk County
Commission Expires August 31, 2013

Abrams, Fensterman, Fensterman, Eisman, Greenberg, Formato & Einiger, LLP
1111 Marcus Avenue, Suite 107
Lake Success, NY 11042